



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/182,102 10/27/98 HAAF

T A-65680-2/RF

EXAMINER

HM12/0228

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BRUSCA, J

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

02/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/182,102

Applicant(s)

HAAF ET AL.

Examiner

John Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2000.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 21 and 47-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 21 and 47-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The rejection of claims 51 and 52 under 35 U.S.C. § 112, second paragraph in the Office action mailed 6/5/00 is withdrawn in view of the amendment received 12/11/00.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. The rejection of claims 18, 19, 21, 47-52, and newly filed claim 53 under 35 U.S.C. § 112, first paragraph for lack of enablement is maintained for reasons of record in the Office action mailed 6/15/00.
4. Applicant's arguments filed 12/11/00 have been fully considered but they are not persuasive. The applicants appear to confuse a rejection for lack of enablement under 35 U.S.C. § 112, first paragraph with a rejection for lack of utility under 35 U.S.C. § 101. A rejection for lack of enablement may be made when undue experimentation would be required of one of skill in the art to make and use the claimed invention. A rejection for lack of utility may be made when there is neither a credible assertion of a specific and substantial utility, nor a well-recognized utility for the claimed invention. The credibility of the assertion is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record. (see Utility Examination Guidelines, Federal Register Vol. 66, No. 4 pages 1092-1099, available at www.uspto.gov). Although a rejection for lack of utility under 35 U.S.C. § 101 necessarily also results in a rejection under 35 U.S.C. § 112, first paragraph for lack of enablement for failure to enable a person of skill in the art to use the invention, the Office may

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deem a claimed invention to meet the minimal requirement of 35 U.S.C. § 101 without meeting the requirements of 35 U.S.C. § 112, first paragraph due to an undue amount of experimentation required of one of skill in the art to make and use the claimed invention. This is the situation in the instant application. The Office action mailed 6/5/00 detailed a Wands factor analysis as to why undue experimentation would be required to make and use the claimed invention. Because the only apparent utility for the claimed invention is as a diagnostic for disease, one of skill in the art would have to use the claimed invention as a method of diagnosing a disease. The applicants state that because Rad51 interacts with other proteins known to be mutated in disease, such as p53, BRCA1, and BRCA2, a mutation in Rad51 also correlates with disease. The logic of this assertion is not apparent. A skilled practitioner would need to establish a correlation between mutations in a Rad51 gene and disease in order to use the claimed method as a method of diagnosis of disease. Absent such a showing by the applicants in the instant specification this would require experimentation of an unguided nature that would be undue.

Claim Rejections - 35 USC § 102

5. The rejection of claim 18 under 35 U.S.C. § 102(b) over Ogawa et al. in the Office action mailed 6/5/00 is withdrawn in view of the amendment received 12/11/00.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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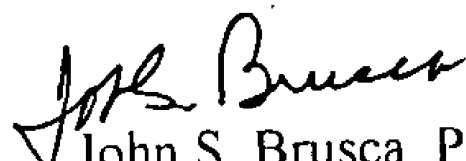
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday -Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


John S. Brusca, Ph.D.
Primary Examiner
Art Unit 1631

jsb
February 16, 2001